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Consultation feedback: Putting Patients First: Modernising health workforce regulation

Overview

The Pharmacy Council welcomes the opportunity to respond to the Minister of Health's consultation that focusses on modernising the health workforce regulation. It is timely to examine the impact of regulation on healthcare delivery, noting that health practitioner regulators are principally held accountable for ensuring individual practitioners are competent and fit to practise, capable of delivering current health services safely.

We agree with the stated aims in the consultation document of ensuring regulators are delivering patient centred, streamlined, right sized, and future proofed regulation.

Improvements could be quickly achieved under the current Health Practitioners Competence Assurance Act 2003 (the Act), such as developing a strong, well resourced, regulatory stewardship function or specifying what further collaboration is needed between Responsible Authorities.

We are conscious that at this stage the consultation document is seeking ideas rather than definitive proposals, and that many of the desired outcomes can only be achieved through coordinated system-wide changes across health, immigration, and education, rather than solely through health regulation reform.

We would also note that some of the suggestions in the consultation document could have unintended consequences, including increased risk to public safety, and may not achieve the desired outcomes of increased health workforce numbers and reduced costs without other sector-wide changes.

Regulators from other countries who have reviewed their role in developing workforce all state the need to work across the health system with other agencies to address workforce challenges and other shared responsibilities, e.g., patient safety. For example in Australia, AHPRA[1] responded as follows to a government-commissioned independent review by Ms Robyn Kruk AO:

'Ahpra and the National Boards will work with our partners across the health system to continue to remove unnecessary barriers for international health practitioners to work safely in Australia. In our complex health system, collaboration with all agencies is the key to achieving systemic change. In sharpening our focus on workforce flexibility and

[1] AHPRA: Australian Health Practitioner Regulation Agency

removing red tape from the registration process, we will continue to prioritise patient safety. Future reforms must always strike a careful balance between safety, fairness, and flexibility.

Following this review, the Australian government has budgeted for significantly more in workforce development than in fiscal support for AHPRA.

Focusing on one component of a complex health system is unlikely to resolve the challenges described in the consultation document. Rather, we advocate for an accelerated development of system-level investment including Regulatory Stewardship at the Ministry of Health, which will improve the understanding of how other agencies and variables contribute to enabling access and supporting safe practice. Greater collaboration across agencies is essential to achieve systemic change and targeted investment in initiatives to optimise regulation, for example, technological solutions to improve regulatory intelligence and, funding of training programmes based on need. Both the Health and Disability Commissioner Act 1994 and Medical Products Bill are under review or development, providing an opportunity for clearer system-level thinking, but we have not seen this.

The Ministry of Regulation describes Regulatory Stewardship *as the governance, monitoring, and care of regulatory systems. It aims to ensure all the different parts of a regulatory system work well together to:*

- *achieve its goals effectively, proportionately, and fairly, and*
- *keep the system fit for purpose over the long term*.

'Agencies need to consider the whole regulatory system' to fulfil their regulatory stewardship responsibilities… *'and proactively work with others to take care of the parts of the system they're responsible for. This includes:*

- *monitoring, reviewing, and reporting on existing regulatory systems*
- *robust analysis and implementation support for any changes to regulatory systems*
- *ensuring good regulatory practice is followed*.

Growing the Ministry of Health's Regulatory Stewardship role will achieve better longer-term solutions, help identify key priorities and provide good evidence to support proposals for change to health practitioner regulation. We attach a separate summary by consultants MartinJenkins setting out pharmacy regulation in the context of Health System Performance (including system stewardship).

Pharmacists specifically are also regulated by Medsafe, (medical products and pharmacy licensing). We have previously called[2] for consideration of regulation of

[2] Pharmacy Council submission on the Therapeutic Products Bill (March 2023).

pharmacists and pharmacies by one regulator to improve efficiency and effectiveness and take this opportunity to ask for this option to be considered.

Given the disruptive and costly implications of setting up a fully amalgamated regulator, we believe that the Minister should take a broader view and consider the case for a range of options between the status quo and full amalgamation.

Introduction

The Pharmacy Council has operated for over 20 years under the Health Practitioners Competence Assurance Act 2003 (HPCAA), and has three scopes of practice: pharmacists, intern pharmacists and pharmacist prescribers. Previously, pharmacy practice (pharmacists and pharmacies) was regulated by the professional body, Pharmaceutical Society of New Zealand, which was also responsible for professional education, and advocacy. Pharmacies are currently regulated by a licensing regime under Medsafe.

Health practitioner regulators must only set requirements that address residual risk of harm, that is, potential harm that is evident despite other measures in place. Each profession has varying levels of professional support which may impact on the level of regulation required to ensure public safety. Professional organisations who previously held regulatory responsibilities now rely on voluntary membership. This has impacted on their ability to support the profession. Inexperienced practitioners and those entering the workforce are vulnerable without adequate oversight or professional support to address the gaps in their knowledge and skills. As registration is focused on the risk associated with entry-level practice, initiatives that support practitioners in the early stages of their practice in New Zealand are likely to support a case for streamlining regulation further.

Adherence to right-touch regulation principles[3] leads regulators to only regulate when necessary, and only when alternative options are unsuitable. When comparing health practitioner regulation in other jurisdictions, other metrics of the health system that support workforce development and safe practice should also be considered, as focusing on regulation alone is unlikely to yield better results. These could include comparison of funding for training practitioners, clinical governance maturity, immigration pathways, workplace support and the level of proactive intervention by professional organisations.

In a 2023 publication, (Safer care for all- *solutions from professional regulation and beyond*), the Professional Standards Authority (UK) includes the following observations that are also pertinent to New Zealand:

[3] Right touch regulation principles- Professional Standards Authority, United Kingdom. (Right-touch regulation | PSA)

To address shortages in the statutorily regulated workforce, governments, regulators, and employers must succeed in retaining existing professionals, recruiting from overseas, creating new roles and training professionals in sufficient numbers. The latter may mean regulators challenging conventions about education and training, and governments setting up clear pathways. Another option may be to look at those working in unregulated roles and consider whether they, with appropriate safeguards, might offer a way forward.

Those involved in health and care workforce planning and delivery across the UK actively support additional and alternative means of assurance as a means of managing risks to patients and service users.

To illustrate the co-dependencies between a regulator and the wider system, we include two recent examples (see over) of reviews by Pharmacy Council of its regulation and the limited resulting scope for change when the focus of resolution is not system-led.

Examples of the limited impact of regulatory changes alone to support workforce development

a) Review of overseas qualification pathway

Typically, each year 10-15% of newly registered pharmacists are overseas pharmacists.

We have a fast-tracked process for pharmacists from countries[4] with similar pharmacy practice and qualification. In response to pharmacy sector workforce demands, we reviewed the qualification pathways for pharmacists from all other countries and compared ourselves with similar jurisdictions.

The reciprocal arrangement for registration between the two countries drives a similar approach to overseas practitioners' registration. Our pathway mirrors the pathway available for pharmacists from the same group of countries wanting to register in Australia, which includes assessment by an examination delivered by the Australian Pharmacy Council.

We made some minor changes (English Language and prior experience requirements) to streamline our processes but had no control over other aspects with a much greater potential for improving uptake and results, such as immigration pathways, availability of components delivered by 3rd parties and access to funding. For example, overseas pharmacists, unlike New Zealand graduates, do not have access to funding for the intern training programme.

Pharmacy practice has changed considerably in the last 40 years, moving from a pharmaceutical science focus to clinical practice. However, the rate of change differs across countries. Pharmacists from countries with qualifications and practice focusing on pharmaceutical production rather than clinical practice struggle to meet the requirements to register in New Zealand. The overall success rate could be improved via a bridging programme (as is available in Canada to prepare candidates for entrance examinations) or a qualification programme (as is required for overseas pharmacists applying to register in the United Kingdom). Such options are demand-led rather than being initiated by the regulator, with education providers typically needing new funding to support direct investment in a programme or indirectly from incentives that attract more applicants.

More broadly, the recruitment and retention of future pharmacists depends on how society values pharmacists and on investing to realise their full potential. Aspects outside Pharmacy Council's control include service commissioning and future workforce decisions (e.g., investment in New Zealand trained versus overseas pharmacists).

[4] Canada, Ireland, United Kingdom and United States. (Australian pharmacists register under the Trans-Tasman Mutual Agreement Act 1997).

b) Review of Pharmacist Prescribers' Scope of Practice

The Pharmacist Prescribers scope of practice authorises advanced clinical pharmacists working in a collaborative health team to prescribe medicines. Starting in 2013, the numbers registered in the scope have slowly increased to 100. Entry and ongoing requirements (including minimum valid practice experience) have been set to reflect the advanced level of practice needed to safely prescribe autonomously.

Recent injection of funding to support general practice workforce has attracted more pharmacists to complete the qualification to register in this scope, which prompted Pharmacy Council to review the entry requirements and conduct a survey of current pharmacist prescribers followed by a focus group.

Pharmacist prescribers supported the current requirements, noting that less experienced pharmacist prescribers may not have adequate professional and work-based support to safely manage expansion of their prescribing practice. In their feedback to Council, they identified constraints (not related to Council's role) to developing pharmacist prescribing. These included the need for greater advocacy, professional support (especially when compared with other prescribers), lack of a career framework and limited sector understanding of the pharmacist prescriber role.

The review supported maintaining the current registration requirements for pharmacist prescribers but to allow exemption for experienced prescribers from a monitoring requirement[5]. Conversely, new registrants that do not fully meet the registration requirements can practise in a narrower scope, with conditions to manage future expansion of practice. Without a more system-based approach to expand pharmacist prescribing, the increase in risk of harm must be managed exclusively by the regulator.

The Pharmacy Council looks forward to work with the sector to identify initiatives that will support safe practice for inexperienced prescribers, leading to possible less conservative future regulation.

The sector, responding to different pharmacist prescribing options available in Canada and piloted in Australia, have called for Pharmacy Council to make prescribing a more widely available option for pharmacists. However, a regulator cannot lead such initiatives but can consider regulation of a prescribing model proposal with evidence of support for its development and implementation in New Zealand.

[5] Relate to Practice Plan requirements.

1. Patient-Centred Regulation

Pharmacy Council manages risk of harm to patients by setting requirements for entry to practice and ongoing practice. Scopes of practice, qualifications and standards are set after extensive consultation. The requirements are set for justifiable public safety reasons and should not cause unnecessary barrier or costs to practitioners. Given the specialised nature of regulation and its interface with healthcare delivery, we receive more feedback from patient advocacy groups rather than individual patients.

This consultation calls for feedback on greater public representation and voice within health practitioner regulation. We support the consideration of options that enable informed-patient input into regulation. Most of our interactions with patients relate to complaints about the service received rather than the requirements we set for pharmacists. Patients want access to safe practitioners and for the regulator to take remedial action when harm is caused, or standards are not met. They recognise that it is the regulator role to hold practitioners accountable for safe professional practice. Patients are unlikely to support lowering the standards of practice to achieve a larger workforce.

Managing risk of harm

Pharmacists play a vital role in minimising the potential harm from medicines and are responsible for more than the supply of medicine. They must also ensure safe dispensing processes, identify prescribing errors, and address unsuitable prescribing. Pharmacists assess the prescription to ensure it is pharmaceutically and therapeutically appropriate, review available patient medical history and medication record, determine whether changes are warranted, and advise the prescriber accordingly. They also counsel individuals on the medicine prescribed, improve compliance with medicines, and provide a further opportunity to validate the safety and appropriateness of the medicine.

The World Health Organisation estimates the global cost of medicine related harm to be $42 Billion (US) which based on population only equates to around $44.7 Million (NZ) cost for New Zealand. Recognising that the information about risk of harm from medication in New Zealand is not well connected across the system, we note one study that estimated medication error is the attributed cause of 2,247 deaths per year in New Zealand. It is also reported in a study that medication-related events prolonged hospital admissions by a mean of 7.8 days; that 43.9% of cases were preventable; and 12.3% resulted in permanent disability or death.

A Health and Disability Commissioner report about medication error complaints identified the proportion of errors attributed to different stages of the medication process as: Prescribing, 33%; Dispensing, 39%; and Administration, 28%. Pharmacists

have a role (under- utilised in New Zealand) to support safe prescribing and administration in addition to dispensing.

When compared[6] with a selection of health practitioner regulators, Pharmacy Council had a moderate total annual formal complaints as a proportion of its registered workforce; (47 complaints is 1.1%) and third highest out of five. Separately, this is lower than the 1.7% proportion reported[7] for the pharmacy profession in Australia.

Most low-level complaints relate to dispensing errors, commonly associated with how an individual manages their practice under workplace pressure rather than a gap in the individual's competence. These generally require an educational letter to support the pharmacist's practice. For more serious complaints, comparison of historical Health Practitioner Disciplinary Tribunal case numbers, indicate that pharmacists represent the second highest regulated profession for annual cases per 4000 practitioners. The prevalence of pharmacy owners amongst these cases suggests that a small number of pharmacists struggle to prioritise professional responsibilities over financial considerations.

Whilst there are opportunities for the health system to make better use of pharmacists to reduce the potential harm of medicines, the Pharmacy Council will continue to ensure that pharmacists are fit and competent to practise to ensure patient safety.

Consumer input

The Health and Disability Commissioner's (HDC) Consumer Advisory Group is currently shared with the Medical Council, but other health practitioner regulators have struggled to duplicate this level of consumer engagement. The Health Quality & Safety Commission (HQSC) Consumer Advisory Group could join with the HDC group to establish consumer input for health practitioner regulation. The Regional Consumer Councils may also provide future opportunities for engagement with health practitioner regulators.

The regulator is held accountable for managing the risk of harm from practitioner practice, and this limits its ability to improve indirect outcomes relating to access. However, we welcome any development that places greater emphasis on identifying all aspects that impact patient outcomes, including better access. This may identify different initiatives with greater impact than changing regulation, e.g., targeted funding.

Currently the health system does not have a unified approach to identifying and understanding the risk of harm from health service delivery. Some risks will directly relate to individual practitioners, but many adverse events relate to system-level deficiencies. The Health Quality & Safety Commission could be given a stronger

[6] *Our insight into five health regulatory authorities*. Office of the Auditor General (2025)- Dental, Medical, Nursing, Pharmacy and Physiotherapy.
[7] Annual Report (Pharmacy Board).

mandate to drive investment in technology to improve the use of data collection to drive system safety and optimise regulatory intelligence. Data- driven regulation supports right touch regulation, i.e., regulation manages the risk of harm with minimal impact on professional practice.

The constitution of a health practitioner board should reflect the expertise needed to direct the regulator in its primary focus on public safety and reflect the specialist professional input needed for application of regulation. Whilst the current legislation allows some regulators to elect members from the profession, we consider that this creates further risks of regulatory capture.

CONSULTATION QUESTIONS- OUR RESPONSE

[We interpret that the questions in this section are not directed at a regulator, and the answers therefore reflect Pharmacy Council's views on consumer/patient input].

Would you be interested in having a say on any of the following?

a. changes to scopes of practice (what health practitioners can do) and how this affects patient care

b. qualification requirements

c. other professional standards (for example, codes of conduct) that impact patient experience

We welcome changes that maximise the opportunity for patients to be involved in health regulation. Patient safety is at the heart of health practitioner regulation, and including patients as much as is practical will support the effectiveness of regulation.

Given the complexity of the health system, we back the development of pathways for patients' voice to be effectively represented, (for example, via Regional Consumer Councils), and welcome opportunities to engage with such groups to further the understanding of the role of health practitioner regulators.

Current legislation requires opportunities for consultation on scopes of practice and qualification but does not specifically refer to members of the public. We include consumer groups in our consultations but note that the public do not always understand the details of regulation, and therefore a greater availability or access to informed consumers will strengthen public input. Pharmacy Council also consults widely on other prospective changes (such as professional standards) and engages lay members for its other committees overseeing regulation in practice.

Are there any other things you think the regulators should consult the public on?

Regulators should consider consulting on any aspect of its regulation that impacts directly on the public.

Are there any health practitioners who are currently unregulated but should be subject to regulation to ensure clinical safety and access to timely, quality care?
This is outside the Pharmacy Council's remit. (See separate comments on regulating pharmacy technicians under section 3. Right-sized regulation).

Do you think regulators should be required to consider the needs of patients and the workforce when making decisions? What are some ways regulators could better focus on patient needs?
All regulation should be proportionate to the risk that it is managing. Better co-ordination of health sector development will improve understanding of the initiatives needed to address the needs of patients and the workforce. The resulting dialogue within the health system will improve understanding of the barriers to change and identify initiatives to support streamlining regulation.

What perspectives, experiences, and skills do you think should be represented by the regulators to ensure patients' voices are heard?
There must be a range of skills and experience in every regulatory authority board or committee. This includes a mix of sector expertise and patient experience, alongside most importantly, people with governance and leadership experience and regulatory understanding. Everyone around the table should have a good understanding of the health system and its complexities, and an in-depth understanding of the relevant legislation. Nominations for new members should be opened regularly, and decisions should be transparent and publicly available.

The current proportion of lay members on regulators' boards is like that for the National Boards in Australia but lower than the 50% for health practitioner regulators in the United Kingdom. Depending on the context and each Board's approach, the current arrangement may limit the public perspective on New Zealand boards. Conversely, a greater proportion of lay members may necessitate more Committees to oversee specialised aspects of the regulator's work.

Do you agree that regulators should focus on factors beyond clinical safety, for example mandating cultural requirements, or should regulators focus solely on ensuring that the most qualified professional is providing care for the patient?
Yes, professional practice is wider than clinical skills and requires effective communication. Practitioners must be clinically and culturally safe to address the health needs of New Zealanders.

Do you think regulators should be required to consider the impact of their decisions on competition and patient access when setting standards and requirements?

Unintended consequences of regulation, such as competition and access, can be identified from effective sector consultation on the development of regulation. Whilst the final decision on regulation is made with the patient's safety as top priority (and non-negotiable), in as far as it can act and influence, the regulator should address such consequences.

Decisions relating to access to service provision is the remit of workforce and service planners and funders rather than regulators. For example, opportunities to reduce rural workforce shortage could be addressed through rural bonding schemes, high-quality training placements, and access to telehealth, rather than regulation.

2. Streamlined regulation

The current legislation includes provisions for amalgamation of some or all health practitioner regulators. Following the 2012 review of the HPCAA, many regulators took the opportunity to share resources, including personnel, office space and technology solutions.

Similar jurisdictions (e.g., Australia, Canada and United Kingdom) have adopted different models of amalgamation across their health practitioner regulators.

AHPRA (Australia) works in partnership with National Boards (15 Boards for individual professions) providing a range of services including policy advice to the National Boards on standards, registration, managing notifications, monitoring Compliance and working with accreditation authorities to ensure suitable skills and qualifications for registration. Whilst the main driver for change was moving from state-based health practitioner regulation to a national (federal) scheme, the states retain some regulatory functions. State-level pharmacy boards are responsible for regulating pharmacies.

The United Kingdom and British Columbia (Canada) maintain profession-specific regulation for some professions including medicine, nursing, dental and pharmacy.

The advantages of amalgamation may include enhanced collaboration, efficiency, resource sharing and consistency. Disadvantages include loss of specialisation or professional identity, complex and costly transition processes, increase bureaucracy, reduced quality of oversight if the amalgamated body is not able to effectively manage the diverse needs of the different health professions.

The pharmacy profession has undergone a significant change in its practice profile in the last 40 years in response to the industrialisation of pharmaceutical production. Pharmacists are now trained to be the medicine expert, but their full potential has not

been realised, where for example, pharmacists would be more actively involved in initiating and managing patients' therapy. Although the Pharmacy Council has limited control over this, amalgamation risks limiting the agility of the pharmacy sector to respond to changes and to realise its potential.

However, the Pharmacy Council is open to consider further options for efficiency gains including amalgamation if necessary, including:

- Shared Services- including technology solutions, office (currently sharing with Dental Council), personnel, etc.,
- Shared functions, e.g., complaints and notification.
- Adoption of common standards and policies. (Pharmacy Council led the development of Principles for quality and safe prescribing practice).
- Sharing regulatory and policy advisors

As mentioned earlier in this response, we consider pharmacy regulation could be more efficient and effective if pharmacists and pharmacies were regulated by one regulator.

CONSULTATION QUESTIONS- OUR RESPONSE

How important is it to you that health professions are regulated by separate regulators, given the potential for inefficiency, higher costs, and duplication of tasks? Why?

The importance may vary for each profession, depending on the inherent risk of harm of practice, level of the profession's self-sufficiency and ability to support practice development. Without details on the level, cost and plans for transition, it is unclear how each profession would be impacted. For example, which 'duplicated tasks' are under consideration; what benefits from the current system could be lost for the potential savings; and what costs would be covered by the Crown and by the professions?

To help improve efficiency and reduce unnecessary costs, would you support combining some regulators?

In principle, yes, but subject to effective management of the risk of harm and continued access to the specialist-level of practice knowledge required to apply the regulation for a given profession.

Health practitioner regulators receive no public funding and are funded entirely through fees paid by the profession. Regulators could be combined if the profession and the public agree that the amalgamation would be beneficial and any risk to public safety would be suitably managed.

3. Right-sized regulation

The Pharmacy Council's approach to regulation of new health professions or services is based on the principles in section 116 of the HPCAA, i.e.:

- an identified risk of harm to the public,
- that regulation is in the public interest
- that those that are seeking regulation, are generally in agreement of the qualifications, standards and competencies required for regulation.

Consequently, the potential regulator of a new profession or service does not initiate or lead such request, but support those considering regulation to understand the purpose of regulation and where applicable, identify alternative options for managing the risk of harm.

However, health practitioner regulators should be agile to respond to a case for change. For example, the Pharmacy Council was asked to consider whether certain pharmacy technicians[8] should be regulated via a separate scope of practice. Advice from an independent consultant indicated that there was not a strong case for regulating this group, as they are supervised by pharmacists. Whilst supervision is less direct for this group of technicians, the risks can be managed via training and clear delegation procedures. These technicians are certified by the Pharmaceutical Society, which is also developing a register for pharmacy technicians.

CONSULTATION QUESTIONS- OUR RESPONSE

Do you agree that these regulatory options should be available in addition to the current registration system?

- ***accreditation***
- ***credentialling***
- ***certification***
- ***any other options***

Yes, these are options suitable for lower risk situations that can be adopted as part of the total regulation of the health workforce. These mechanisms could also be adopted to a greater extent by currently regulated health practitioners as alternative solutions for regulating evolving practice and specialisation, instead of new scopes of practice and standards. (Currently, the relative level of adoption of these mechanisms varies across the professions).

[8] Pharmacy Accuracy Checking Technicians- pharmacy technicians trained to have the final check of dispensing after a pharmacist has assessed the clinical safety of the prescription.

Do you think New Zealand's regulatory requirements for health workforce training, such as the requirement for nursing students to complete 1,000 hours of clinical experience compared to 800 hours in Australia, should be reviewed to ensure they are proportionate and do not create unnecessary barriers to workforce entry?
Comparing the quantum of hours required to upskill to the required standard of competence in two different jurisdictions is arbitrary and the New Zealand requirements are not necessarily excessive. Practice context such as difference in the level of workplace support and training, for example, may dictate the difference in requirements.

Should the Government be able to challenge a regulator's decision if it believes the decision goes beyond protecting patient health and safety, and instead creates strain on the healthcare system by limiting the workforce?
There are current mechanisms to challenge unnecessary regulation under primary legislation that could be streamlined or more actively exercised, (e.g., provisions within HPCAA and Legislation Act 2019). Active engagement in early discussions with the wider health sector (possibly mandated) about the development of regulation and active participation in consultation processes would limit the need for late intervention.

Do you support the creation of an occupations tribunal to review and ensure the registration of overseas-trained practitioners from countries with similar or higher standards than New Zealand, in order to strengthen our health workforce and deliver timely, quality healthcare?
The Professional Standards Authority in the United Kingdom reviews the work of the UK's professional regulators to improve regulation and gives policy advice to government and others and encourage research to improve regulation. Its powers include review decisions about individual practitioners at the High Court. The Pharmacy Council does not object in principle to decisions being overturned by a similar agency, in so far as the new decision-maker is held accountable, as the revised decision may change the risk of harm.

Should the process for competency assessments, such as the Competence Assessment Programme (CAP) for nurses, be streamlined to ensure it is proportionate to the level of competency required, allowing experienced professionals who have been out of practice for a certain period to re-enter the workforce more efficiently, while still maintaining clinical safety and quality of care? If so, what changes should be made?
This depends on the details for the specific context and risk for nurses returning to practise, so we have no further comment.

Do you believe there should be additional pathways for the health workforce to start working in New Zealand?

There are opportunities to expand the health workforce within New Zealand. For example, an earn-as-you-learn pathway, with dedicated mentoring and professional development could help to progress people into more clinical roles.

However, whilst a health practitioner regulator should be agile to respond to a case for change, it is not within its remit (nor should it be) to initiate new pathways.

4. Future-proofed regulation

CONSULTATION QUESTIONS- OUR RESPONSE

Do you think regulators should consider how their decisions impact the availability of services and the wider healthcare system, ensuring patient needs are met?

Public safety is key to all regulatory decisions. Availability of services and meeting patient needs are the remit of commissioners (those who fund and plan the health system) rather than regulators.

There is nothing in the current legislation that prevents patient-centric innovations, such as integration of clinical pharmacists within a general practice team, to be created by the sector and supported by the regulation.

Do you think the Government should be able to give regulators general directions about regulation? This could include setting priorities for the regulator to investigate particular emerging professions, or qualifications from a particular country to better serve patients' healthcare needs

Yes, to responding to a statement of expectations and using allocated new funding to support the direction for the whole sector, but it may not be appropriate for regulators to initiate these processes using practitioner funding when there isn't a robust business case for regulatory change.

The professional regulation model widely adopted, especially in jurisdictions with similar governance and public expectations to New Zealand, offers an adaptive and responsive model. Under professional regulation, regulators must retain independence to ensure decisions for competence assurance are made on behalf of patients to ensure safe practice.

Do you think the Government should be able to issue directions about how workforce regulators manage their operations, for example, requiring regulators to establish a shared register to ensure a more efficient and patient-focused healthcare system?

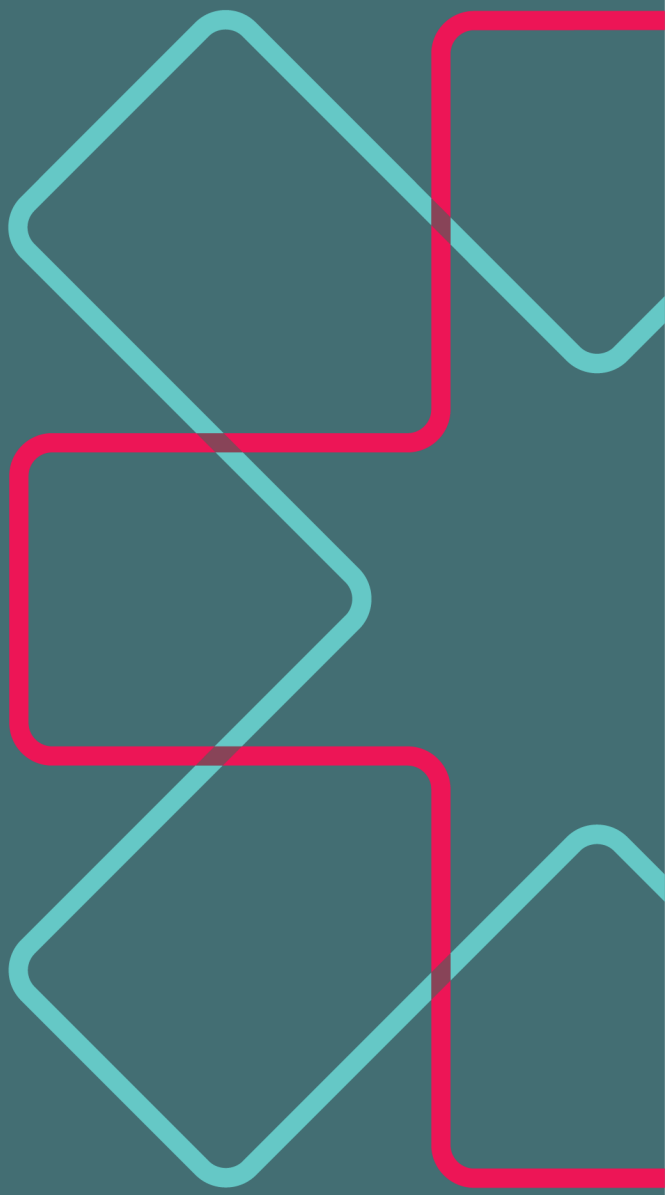
Regulators should always consider operational improvements to maintain effectiveness and efficiency and have demonstrably engaged with the Ministry to accommodate previous Government directions. The HPCAA includes provisions for auditing and amalgamation that could be exercised as a last resort, should a regulator be resistant to a reasonable case for change, for example, when the Government is funding initiatives to avoid cross-subsidising by other professions.

Do you think the Government should have the ability to appoint members to regulatory boards to ensure decisions are made with patients' best interests in mind and that the healthcare workforce is responsive to patient needs?

It is not within the regulator's remit to address these aspects directly. Effective governors that understand the health sector and the role of the regulator are best placed to ensure the regulator manages public safety without creating unnecessary barriers to practice.

Pharmacy Regulation and Health System Performance

Final Report



MARTIN JENKINS

30 April 2025

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Preface

This report has been prepared for The Pharmacy Council by Michael Mills from MartinJenkins (Martin, Jenkins & Associates Ltd).

For over 30 years MartinJenkins has been a trusted adviser to clients in the government, private, and non-profit sectors in Aotearoa New Zealand and internationally. Our services include organisational performance, employment relations, financial and economic analysis, economic development, research and evaluation, data analytics, engagement, and public policy and regulatory systems.

We are recognised as experts in the business of government. We have worked for a wide range of public-sector organisations from both central and local government, and we also advise business and non-profit clients on engaging with government.

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Established in 1993, we are a privately owned New Zealand limited liability company, with offices in Wellington and Auckland. Our firm is governed by a Board made up of Executive Partners and Independent Directors. Our Independent Directors are Jenn Bestwick and Chair David Prentice. Our Executive Partners are Sarah Baddeley, Nick Carlaw, Allana Coulon, Nick Davis, and Richard Tait. Michael Mills is also a non-shareholding Partner of our firm.

Context

The Minister of Health is focussed on improving the operation of the health system to put patients first and support frontline healthcare workers to deliver the healthcare New Zealanders need in a timely and quality manner.

To this end, the Health Practitioners Competence Assurance Act 2003 (HPCAA) and its administration by 18 independent regulators including the Pharmacy Council is being reviewed to ensure the focus is on putting patients first.

To inform its submission to the review, the Pharmacy Council engaged MartinJenkins to consider the regulation of pharmacists within the wider health system, and to consider how the Pharmacy Council might ideally operate within this system and with other regulators to deliver on government objectives to improve operation and performance of the New Zealand health system.

A particular focus of this paper is the contribution that occupational regulation and occupational regulators can make to the improved supply and management of health workers.

Government health system objectives

The Government wants the health system to deliver timely and good quality healthcare for all New Zealanders. A key focus for the Minister of Health is practical changes that can be made to streamline access to health services so that patients receive the care they need when they need it.

Improvements to the operation of the health system are being made within a fiscally constrained context. This means that those with roles in the operation of the health system need to perform them efficiently and effectively. The government has also made it a priority to remove unnecessary barriers and costs to the provision of accessible health services and to ensure that systems and processes necessary for access to quality services are operating efficiently.

For its review of modernising health workforce regulation, the government wants to ensure that regulatory settings and their administration are:

- **Patient-centred** – by ensuring regulatory settings and their administration are informed by the experiences and expectations of New Zealanders in accessing health services, and that regulators are accountable for the performance of their regulatory activities.
- **Streamlined and cost-effective** – by ensuring that the system is set up to operate efficiently and cost-effectively in its administration of regulatory activities.
- **Right sized and risk-based** – by ensuring that the scope of regulatory requirements is proportionate to risk, does not create unnecessary red tape where risk is low and the need for regulation is low, or slow down the provision of health services resulting in worse outcomes for patients.

- **Future focussed** – be ensuring that regulatory settings and requirements are not unnecessary obstacles to harnessing new technologies and innovative approaches to the delivery of health services.

Regulation of pharmacists

There are around 4,500 practising pharmacists in New Zealand. Pharmacists are experts in medicine. They prepare, mix, check, and dispense medications; provide advice on medicines, health issues, and lifestyle choices; and provide core health services like vaccinations and health screenings.

The Pharmacy Council regulates pharmacists under the relevant provisions of the HPCAA. The Council is one of 18 specialist health profession regulators in New Zealand (including the Dental Council and Paramedic Council).

The HPCAA provides a mechanism whereby the scope of practice and competencies of its practitioners, expected standards, and the education and skill requirements are carefully prescribed. Accordingly, regulation under the HPCAA enhances consumer safety and knowledge by providing the public with a reliable, current source of information regarding standards to be expected of the profession and by allowing identification of competent and qualified providers.

Under the current legislation the purpose of regulating pharmacists is to protect the health, safety and wellbeing of the public by ensuring pharmacists are competent and fit to practice. This is achieved by:

- Defining the three scopes of pharmacy practice: Pharmacist, Intern Pharmacist and Pharmacist Prescriber. The scopes outline the specific health services each category of pharmacist is qualified to provide, ensuring safe and effective medication use and health outcomes. Pharmacy technicians and retail pharmacy assistants are not required to be registered or licensed and can only operate under the supervision of pharmacists.
- Setting competence standards which specify the minimum core foundational knowledge, skills and attributes required of pharmacists upon registration into a scope of practice and the minimum requirements to safely and effectively carry out the range of health services that a pharmacist is authorised to provide.
- Accrediting and monitoring educational institutions in their delivery of education and training programmes to pharmacists.
- Assessing qualifications of internationally trained pharmacists (two routes - Recognised Equivalent Qualification Route and Non-Recognised Equivalent Qualifications Route.
- Registering pharmacists.
- Issuing annual practice certificates and setting recertification requirements.
- Administering processes for pharmacists to return to practice after a period of absence from practice.

- Receiving, investigating and, if necessary, acting on reported concerns about a pharmacist's practice, health, conduct or competence.

Regulation of pharmacies

Pharmacies are also regulated by Medicines Control (part of MedSafe) through provisions in the Medicines Act 1981. The responsibilities of Medicines Control include:

- Licensing and Monitoring: They ensure that pharmacies comply with legal and professional standards by issuing licenses and conducting regular inspections.
- Compliance and Enforcement: They monitor pharmacies to ensure they adhere to the Medicines Act and other relevant regulations, taking enforcement actions when necessary.
- Quality Assurance: They oversee the quality and safety of medicines supplied to the public, ensuring that pharmacies maintain high standards in storage, handling, and dispensing of medications.
- Education and Guidance: They provide guidance and support to pharmacists and pharmacy staff to help them understand and comply with regulatory requirements.

Relationships with other organisations

In the performance of its regulatory activities the Pharmacy Council works closely with:

- Other health practitioner regulators.
- Pharmacist professional associations such as the Pharmaceutical Society of New Zealand and Pharmacy Guild.
- Health Practitioner Disciplinary Tribunal.
- Health and Disability Commission.
- Medicines Control (licensing and regulation of pharmacy premises).

Concerns for occupational regulation

Concerns with the current approach to regulation of the health workforce are discussed in the consultation document "Putting Patients First: Modernising health workforce regulation". In summary, these concerns relate to:

1. A lack of public involvement and transparency in the setting and administration of regulatory requirements.
2. Cost and inefficiency in the administration of regulatory requirements from having 18 specialist regulators each with separate processes and systems.
3. Regulatory barriers to entry to the health workforce and delivery of some health services – and a view that the current system results in a 'one sized' rather than a 'risk-based' approach to regulation creating barriers and costs to entry (including for overseas health professionals and returning workers) and limiting integrated approaches to service delivery across professions and disciplines.
4. Concerns that current approaches to regulation may be barriers to future health system innovation and change – because regulatory standards and requirements embed current ways of working and delivering services and make it hard to innovate.

While occupational regulation is important to the operation of the health system, **a whole of system approach** is needed to deliver better patient outcomes

Regulation of pharmacists is an important component of a complex health system. Done well, it helps ensure the safety of patients in their use of medicines.

The approach taken to occupational regulation can contribute to (or hinder) broader workforce and health system outcomes and objectives.

The Pharmacy Council exists and operates within the broader health system and in relation to workforce supply aspects, alongside the education and immigration systems. Changes to regulatory settings alone will not be sufficient to deliver a sustainable health workforce, to provide for better patient experiences in accessing health services, and to reduce costs of providing health services.

Other regulatory settings that influence the health workforce and premises

Key regulatory and other settings that impact on the health workforce, approaches to service delivery and cost include:

- **Tertiary education and training** policies, funding mechanisms and investment plans, that provide for and constrain the education and training and supply of pharmacists. While the Pharmacy Council specifies the competence standards required of pharmacists, the Tertiary Education Commission determines the amount of funding available for university medical courses, and it is the two universities offering pharmacy degrees that decide the number of pharmacist places and the criteria for being admitted to an available place.
- **Immigration settings** for entry of overseas health practitioners to work in New Zealand. While the Pharmacy Council specifies the competency requirements and qualifications for overseas pharmacists to work in New Zealand (including administration of the overseas registration routes), the process of administering immigration requirements and issuing visas is administered by Immigration New Zealand.
- **Funding, procurement, and contractual** arrangements for provision of different health services, that set expectations for coordination and integration across services areas and limit and provide for and constrain the scope of practice areas and service provision – such as procurement and funding arrangements for vaccinators under the Medicines Act that provide for some pharmacists to administer flu vaccinations.
- **Operational policies, standards, codes** and other regulatory requirements that set expectations for and constrain the delivery of health services including requirements of the regulation of pharmacy premises as set out in the Medicines Act 1981.
- **Decisions to regulate other professions** for example pharmacy technicians, sit with the Minister of Health and are often influenced by the desire of that profession to be regulated. Regulation places a cost on the profession through the requirements to pay annual fees therefore the benefits of regulation need to outweigh these costs.

Possible changes

Changes to pharmacist regulation and its administration may help address some of the issues driving the review of occupational regulation but will not fully address all the concerns without greater alignment and coordination with others in and adjacent to the health system. For instance:

- Changes to qualification requirements may make it easier for some students to enter the profession, and for some persons with overseas qualifications and experience to practise in New Zealand. Such changes will not alone provide a sustainable solution to addressing shortages of pharmacists. Instead, a coordinated approach with education and training providers, immigration policy makers, employers, funders and other regulators is needed to develop a sustainable approach to addressing workforce supply issues and delivering a sustainable workforce.
- Changes to scopes of practice, competency requirements, Codes and other requirements might make it easier for pharmacists to provide more allied services, or for non-pharmacists to dispense

some medicines, but without changes to commissioning and funding arrangements there is likely to be limited take-up of these services particularly in community pharmacies.

Case study example

One example of how the Pharmacy Council has worked with others to address workforce challenges is with the University of Waikato, which developed a Master of Pharmacy Practice programme designed to provide an alternative route, including for some internationally trained pharmacists, to practise in New Zealand. This is the first graduate-entry pharmacy programme in New Zealand, aimed at addressing the pharmacy workforce shortage.

The programme integrates academic learning with practical pharmacy practise, including community, primary care, and hospital placements under the supervision of clinical academic pharmacists. The programme is a two-year, 240-point course that includes 375 hours of practical pharmacy experience. The University has worked with the Pharmacy Council to gain accreditation, and graduates are eligible to apply for registration as an Intern Pharmacist with the Pharmacy Council of New Zealand. After completing the Intern Training Programme, they can apply for full registration as a pharmacist.

System stewardship is critical to the effective operation of the health system

A well performing health system is important to the well-being of New Zealanders. Regulatory stewardship is the governance, monitoring and care of our regulatory systems. Regulatory systems are intended to be assets for our communities but, like most other kinds of assets, they need regular ongoing care and maintenance if they are to deliver best value to New Zealanders.

Stewardship is one of the five principles outlined in the Public Service Act that Chief Executives are responsible for upholding. Stewardship in this context includes considering long term capability and its people, institutional knowledge and information, systems and process, assets, and legislation.

The Government's expectation for regulatory stewardship set out responsibilities in three broad areas:

1. Monitoring, reviewing and reporting on existing regulatory systems
2. Robust analysis and implementation support for changes to regulatory systems
3. Good regulatory practice.

The complexity of the health system, the interdependence between system components and the system's reliance on public funding mean that effective system level stewardship is critical to the effective operation and performance of the health system.

The Ministry of Health has an important role as the health system steward, in clearly setting expectations and monitoring operation and performance of the system, advising on government funding of health services, in ensuring alignment and coordination across different parts of the system and in providing leadership and support for change and innovation.

System level stewardship, including system level strategies, plans, policies, expectations, performance requirements and monitoring, are all critical to ensuring better integrated and coordinated approaches to workforce planning and supply in respect of issues such as capacity and capability forecasting, workforce planning, recruitment and training, and flexible use of health practitioners.

To the extent that workforce supply issues are critical to the performance of the health system, a strategic and well-coordinated approach to their resolution is necessary. This needs central leadership and must involve all with roles to play in the supply of health professionals including those involved in their training, the funding of their training, their employment and their regulation.

Roles and responsibilities for issues related to occupational regulation

In the table below we summarise our thinking on the role of regulators and others in addressing the concerns at the heart of the government's review of health workforce regulation.

Area of concern	Role of regulator	Led by others with regulator support
Insufficient public involvement in the setting and administration of regulatory requirements.	Explore options to better inform itself of patient expectations and experience of pharmacists. Give greater weight to patient experience and expectations in the setting of competency requirements and training.	
Administrative cost and inefficiency in the administration of regulatory requirements by 18 specialist regulators.	Establish shared service arrangements across health workforce regulators that achieve efficiency whilst maintaining effectiveness.	
High regulatory barriers to participation in the health workforce and delivery of some health services.	Review existing standards, qualification requirements and processes to ensure that these are not resulting in unnecessary barriers to entry especially for those with international qualifications.	Develop and implement a coordinated strategy to increase supply and retention of health professionals involving regulators, TEC, INZ, HNZ and the MoH.

Concern that the current approaches to regulation may be barriers to future innovation and change	Review scopes of practice to ensure that innovative service delivery and provision of new services is not limited or enabled.	Consider a more proactive stewardship role of the Ministry of Health. Consider whether alternative forms of regulation could be applied to other roles within pharmacy (e.g. technicians) to enable expanded service delivery.

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